GD052
OpenClinica Data Changes

The purpose of this document is to provide guidance on making data changes in OpenClinica.

Whilst the process may differ between OC3 & OC4 the concept of this is expected to be the same; this guidance document has been written for OC3 and will be updated in the future to specifics of OC4 where necessary.

This guidance document provides a procedure to address situations when a data change is required that cannot be made by the data originator (usually the site data entry delegate).

IMPORTANT NOTE: Study data managers should not be amending any of the site data, including annotation notes, or marking eCRFs as complete. Unless they are on the site delegation log, a study data manager should not appear on the site data audit without a documented reason.

There are various circumstances where a data change may be required during a study, some of these scenarios are covered in the appendix. However, the procedure for requesting a change to data is outlined below and should always be adhered to.

The procedure for changing data:

1. The request to change data should be reviewed and fully understood by the study data manager (or member of the data team making the change). If necessary, the study data manager should discuss the change with the Data Manager Lead (DML), the Senior Clinical Data Manager and the Clinical Project Manager (CPM).
2. The change should be documented on FRM039 Data Changes on eForms. For further guidance on which of the eForms to use please see GD023 eForms system for study documents.
3. At this stage of the request FRM039 requires the completion of the following fields:
    a. Subject ID – consider if more than one subject ID requires the exact same change then it is acceptable to add more than one subject ID to this field, if the change is not exactly the same then a new line should be created for each change.
    b. eCRF name that requires the change - if no eCRF requires change for example, it is the event that requires change, this field can be marked as n/a.
    c. Field name of the data – if no data field requires change for example, it is the eCRF or event that requires change, this field can be marked as n/a.
    d. The change requested for the data.
    e. Reason for change – this field must be completed with relevant details, sufficient to help the authorising user understand the reason for the request. Also record who has requested the change for example a member of the site team, the trial manager or another.
    f. Name of the person submitting the data change request, along with the date of request.
4. The data change request should be authorised by the study's clinical project manager (see note below) using their own OpenClinica account. Authorisation will require the Clinical Project Managers name and authorisation date.
5. The study data manager can action the change once authorisation is provided.
6. The study data manager **must update** the FRM039 Data Changes form and record the action taken in the **note's** column, for example 'Subject ID amended to RB001', their name and the date the change was made.

NB: If the Clinical Project Manager (CPM) is unavailable and the request is time-sensitive, another Clinical Project Manager may authorise simple changes (you will need to ensure that they have access to the study on eForms). For more complex changes requiring deeper study knowledge, authorisation can be sought from the Senior R&D Manager or the Clinical Trials Unit Operational Manager.

OpenClinica Audit Log: OpenClinica has an inbuilt audit log that records all actions to ensure all data is traceable. The audit log shows the initial entry of data and any changes that have been made, by whom (username, role, organisation), when (date/timestamp) and why (the reason for change). This provides a means for checking that the above instructions have been followed.

Important notes:

- Where the term 'study data manger' has been used, actions can be carried out by another member of the data management team as appropriate.
- No changes should be made by the sponsor team when the change can be made by the site staff.
- No changes should be made without authorisation of the FRM039.
- No changes should be made once the Principal Investigator has signed off site data ahead of an interim analysis or a database lock.

Appendix A

Examples of Data Change scenarios:

1. **Subject ID entered incorrectly**
    a. Site staff may enter the format of a subject ID incorrectly, rather than deleting the entry, the subject ID can be edited.
    b. FRM039 should be completed by the study data manager and the Clinical Project Manager notified to authorise the change request.
    c. In this situation, if delaying the change could cause further errors, such as duplicate entry of a recruited subject to OpenClinica or inconsistent ID numbering, correcting the subject ID before Clinical Project Manager approval is allowed however it is not a preferred method of completing a data change. For CTIMPs, the study data manager should seek authorisation from the data manager lead or the senior clinical data manager prior to making this change, this individual should add their initial and authorisation for the change to the **FRM039 reason for change** data field (in order to show in the eForms audit log).
    d. The subject id can be edited by viewing the subject that requires the change, selecting the **study subject id**, selecting **edit record** and over typing the **study subject id** data field.
    e. Pause to consider that the changes made are correct and select the **confirm changes** icon.
    f. Comments in the **notes** section of FRM039 should explain why the change was made before CPM approval and describe the change. In the **amended by** and **date** field, include your name and amendment date.

2. **Removing an event scheduled in error**
    a. An example is a patient who has ended study however an additional visit or follow up event was scheduled on OC which the patient will not be available to complete.
    b. FRM039 should be completed by the study data manager and authorised by the Clinical Project Manager.

c. The status of the event should be changed to **stopped** (this highlights the status of the event as being changed), by selecting the **edit** icon in the actions column and selecting **stopped** from the **status** drop down box and selecting **submit change.**
d. If no further data is expected to be added to the event the event can be removed by selecting the **blue cross** icon in the **action's** column.
e. The actions taken should be fully recorded in the FRM039 **notes** section, in the **amended by** and **date** field, include your **name** and **amendment date**.

3. Data entered in the wrong event

a. An example of this is when the discharge data for subject ID RPH010 is incorrectly recorded under subject ID RPH011 discharge event.
b. The FRM039 should be completed by the study data manager and authorised by the Clinical Project Manager.
c. The study data manager should review the data entered in the incorrect subject IDs eCRFs, making sure it has been identically transcribed into the correct subject IDs eCRFs.
d. This can be done by opening a view only copy of each eCRF and viewing each window alongside the other or using data gathered through Insight. If there are any differences between the data, these should be queried with the site by creating a discrepancy note.
e. Only when the sets of eCRF data for the event have been compared, should the event that was completed in error be removed. The event that has been completed in error, will indicate which steps you should follow next:
    i. If the participant is still expected to complete this event at some point in the future, the status of the event should remain as scheduled or data entry started, each of the events eCRFs should be removed by selecting the **red cross** icon in the **action's** column associated with the eCRF. The event should be monitored by the study data manager to check that data is entered at the correct time point by the site staff and that they should change the start date for this event when it takes place.
    ii. If the event is not expected be completed, for example the subject has already been withdrawn for the study, then follow the actions in section '2. Removing an event scheduled in error'.
    iii. If the event is still expected to be scheduled as detailed in (i) but it does not take place, then the visit should be deleted (a new data change request will be required for this prior to deleting the event).
    iv. The actions taken should be fully recorded in the FRM039 **notes** section, in the **amended by** and **date** field include your **name** and amendment **date.**

4. Data entered in the wrong eCRF

a. The FRM039 should be completed by the study data manager and authorised by the Clinical Project Manager.
b. No data should be removed from an eCRF prior to the study data manager reviewing the data entered in the incorrect subject IDs eCRF and making sure it has been identically transcribed into the correct subject IDs eCRF.
c. This can be done by opening a view only copy of each eCRF and viewing each window alongside the other or using Insight. If there are any differences between the data, add discrepancy notes to query the difference with the site.
d. Only when the two sets of eCRF data have been compared, should the eCRF that was completed in error, be removed by selecting the **red cross** icon.
e. Pause to reflect the change you about to make is correct and select **confirm.**

f. The eCRF will reset to data entry started and is ready for further correct data entry when required.
g. If the eCRF is still expected to be completed the study data manager should watch to ensure this is completed.
h. The actions taken should be fully recorded in the FRM039 **notes** section, in the **amended by** and **date** field, include your **name** and amendment **date**.

5. Locking an event in error

a. An example of this scenario is when, in preparation for an interim analysis, some events in the database are locked while others remain unlocked. The wrong event may unintentionally be locked.
b. The FRM039 should be completed by the study data manager and authorised by the Clinical Project Manager.
c. The row of the event should be located, in the **action's** column select the **edit** icon, check the subject id and event are correct for the details requested in the change, select the dropdown option in the **status** data field and choose the status that the event should be restored to.
d. The status selected will be the status of the event prior to the event being mistakenly changed to locked.
e. Pause to reflect the change you about to make is correct, and select **confirm**, the event will now show as unlocked and the status will be as it was prior to being changed to in error.
f. The actions taken should be fully recorded in the FRM039 **notes** section, in **amended by** and **date** field, include your **name** and amendment **date**. This should also be noted in the data competition spreadsheet.

6. Removing a subject ID

a. An example scenario is when site have added a subject ID in error. For example, entering the subject ID incorrectly adding a patient that has already been recorded in OpenClinica.
b. Usually, the subject ID would be amended by the study data manager however, sites may not notify you of this and create a new ID resulting in duplicate subject IDs (the meaning of duplicate is a recruited patient already recorded in OpenClinica).
c. The FRM039 should be completed by the study data manager and authorised by the Clinical Project Manager.
d. The subject ID should be reassigned to the **test** site of the study.
e. Once reassigned to the test site, the subject ID should be removed using the **blue x icon**.
f. The actions taken should be fully recorded in the FRM039 **notes** section, in **amended by** and **date** field, include your **name** and amendment **date**.

7. Removing a table row from an eCRF

a. An example of this scenario is when the site has added a row of medication data to the table in the ConMeds eCRF in error.
b. In OpenClinica 3, the option for any user to remove one row of data from a table is removed once the CRF has been saved.
c. The site staff (not the study data manager) will be required to edit the eCRF and remove data from each data field in the row. A reason for change discrepancy note / query (see GD053 Discrepancy Notes) will need to be created for each data field that is being changed and the eCRF saved.
d. In OpenClinica 4, rows in tables or common repeating events can be removed by users (ideally this will be the site staff) with the edit permission. However, a pop-up tab will display as ***'Delete this***

group of responses? *This action is irreversible (it will be recorded in the audit trail). Are you sure you want to proceed? If so, please enter a reason for deleting the group.'* Once a reason is provided, the row can be deleted. All data entry activities can be seen in the audit trail.